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EXAMINER				
EPFS -SMITH, JANET L				
ART UNIT		PAPER NUMBER		
1633				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary

Application No.

10/582,915

Applicant(s)

KIM ET AL.

Examiner

Janet L. Epps-Smith

Art Unit

1633

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-12 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 1-12 are presently pending. Claims 1-12 were examined only to the extent that they read on elected inventions involving SEQ ID NO: 1-6, and SEQ ID NO: 84-87.

Response to Amendment/Arguments

Specification

2. The objection to the specification as set forth in the prior Office Action is withdrawn in response to Applicant's amendment to the specification filed 02/25/2009.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3 and 5-12 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Written Description).
5. In the reply filed 02/25/2009 Applicants traversed the instant rejection by means of amending the claims to delete the phrase "(c) a nucleotide sequence which has an identity of at least 80% to a sequence of (a) or (b)." However, to the extent that the instant claims encompasses "(d) a nucleotide sequence which hybridizes under

stringent conditions to a sequence of (a), or (b)," wherein the nucleic acid is of undefined length and hybridizes under undefined "stringent conditions," it remains that the instant claims encompass sequences of undefined complementarity to SEQ ID NO: 1-17 and their complementary sequences.

It remains that the scope of the instant claims therefore encompass nucleic acids of any form, antisense, siRNA, dsRNA, microRNA, precursor molecule microRNA, or any other form of isolated nucleic acid comprising a nucleotide sequence that hybridizes under undefined stringency to SEQ ID NO: 1-17 (although only SEQ ID NO: 1-6 were searched), or hybridizes to the complement of SEQ ID NO: 1-17.

The instant specification does not provide adequate description of the full scope of isolated nucleic acids which hybridize to SEQ ID NO: 1-17 or complements thereof, encompassed by the instant claims, because neither the specification nor the prior art disclose the specific nucleotides that are essential to the claimed invention, particularly wherein the claimed isolated nucleotides are microRNAs or precursor molecule microRNAs, and further wherein said isolated nucleic acid sequences are useful in determining the differentiation state of human embryonic stem cells. Without such description, the skilled artisan would not be able to envision what positions within SEQ ID NO: 1-17 can be inserted, deleted or modified to produce a variants of nucleic acids of the instant invention, wherein said variants "hybridize" under undefined stringency conditions to SEQ ID NO: 1-17 or complements thereof, remains a microRNA or precursor molecule microRNA, and are useful for determining the differentiation state of human embryonic stem cells (see page 17, lines 18-25 of the specification as filed).

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In order for the written description provision of 35 USC 112, first paragraph to be satisfied, applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed. For example, MPEP 2163 states in part,

"An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.")"

Because the essential structural features necessary to microRNA processing elements and the nucleotide positions essential to the function of SEQ ID NO: 1-17 are unknown, the skilled artisan cannot envision the detailed structure of the encompassed isolated nucleic acid molecules.

6. The rejection of claims 13-14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's cancellation of these claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1-2, and 5-11 remain rejected under 35 U.S.C. 102(a) as being anticipated by Houbaviy et al. (August 2003).

9. Applicant's arguments filed 02/25/2009 have been fully considered but they are not persuasive. Applicants traverse the instant rejection by means of amending the instant claims to remove the phrase: "(c) a nucleotide sequence which has an identity of at least 80% to a sequence of (a) or (b)." However, to the extent that the instant claims encompasses "(d) a nucleotide sequence which hybridizes under stringent conditions to a sequence of (a), or (b)," wherein the nucleic acid is of undefined length and hybridizes under undefined "stringent conditions," it remains that the instant claims encompass sequences of undefined complementarity to SEQ ID NO: 1-17 and their complementary sequences. Absent evidence to the contrary, since the miRNA sequences of Houbaviy et al. comprises an identity of at least 80% to a sequence of SEQ ID NO: 1-6, the sequences of Houbaviy et al. would also be expected to read on the instant claims to the extent that they read on isolated nucleic acid sequences which hybridize under stringent (albeit undefined) conditions to the nucleotides sequences of SEQ ID NO: 1-6 and/or complements of SEQ ID NO: 1-6.

As stated in the prior Office Action, Houbaviy et al. teach that the isolation, cloning, and sequencing of three libraries of miRNA sequences. In one particular aspect, Houbaviy et al. disclose the following miRNA from embryonic stem cells:

miR-302: UAAGUGCUUCCAUGUUUUGGUGA. SEQ ID NO: 2, 4, and 6 of the instant application are at least 80% identical to the prior art miR-302, see the following alignments, the nucleotides in bold are identical to the prior art sequence:

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miR-302b **UAAGUGCUUCCAUGUUUUAGUAG** (SEQ ID NO: 2)miR-302: **UAAGUGCUUCCAUGUUUUUGGUGA** (prior art)miR-302b **UAAGUGCUUCCAUGUUUUCAGUGG** (SEQ ID NO: 4)miR-302: **UAAGUGCUUCCAUGUUUUUGGUGA** (prior art)miR-302d **UAAGUGCUUCCAUGUUUGAGUGU** (SEQ ID NO: 6)miR-302: **UAAGUGCUUCCAUGUUUUUGGUGA** (prior art)

Claim Objections

10. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633